

Application No. 09/553,573
Amendment October 9, 2007
Reply to Office Action of July 9, 2007

REMARKS

Applicant amended independent claims 1, 102, and 147 to further define Applicant's claimed invention. Support for the amendments to claims 1, 102 and 147 can be found at least in FIGS. 4 and 5 of the application.

In the Office Action, the Examiner rejected claims 1, 2, 4-8, 11-34, 36-38, 40-42, 101-130, 132-135, and 137-174 under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a), as being obvious over U.S. Patent No. 6,113,638 to Williams et al. ("Williams").

Applicant amended independent claims 1, 102, and 147 to recite "said implant during insertion between the adjacent vertebral bodies having an insertion height transverse to the mid-longitudinal axis and transverse to the width of said implant, said implant when fully installed between the adjacent vertebral bodies having a maximum height transverse to the mid-longitudinal axis and transverse to the width of said implant being the same as the insertion height." Williams does not disclose or suggest such structure.

Williams teaches an implant including "a first anchor plate 132, a second anchor plate 134, and a cage comprising an upper cover 138 and a bottom plate 140," and a plurality of anchoring elements 142. (Williams, col. 8, lines 22-25; FIG. 7A). FIG. 8A of Williams shows that when the implant is inserted between the adjacent vertebral bodies, anchoring elements 142 are retracted in the interior of the implant and do not extend from either upper cover 138 or bottom plate 140. FIG. 8B shows that when the implant is fully installed, anchoring elements 142 "are introduced into the vertebrae by applying a force with fixation screws 146 to the anchor plates," and the implant "is anchored between the adjacent vertebrae L4 and L5 by the anchoring elements 142 penetrating vertebral end plates E4 and E5." (Williams, col. 9, lines 20-23).

In Williams, the insertion height of the implant of FIG. 7A during insertion between the vertebral bodies (FIG. 8A) is less than the maximum height of the implant when fully installed (FIG. 8B). The other embodiments of implants of Williams shown in FIGS. 1, 2, 3A, 3B, and 5A are also inserted between the adjacent vertebral bodies with the anchoring elements retracted in the interior of the implants and not extended from the upper and lower surfaces of the implants. When the implants of FIGS. 1, 2, 3A, 3b, and 5A are fully

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installed between the adjacent vertebral bodies, the anchoring elements of the implants are extended through the upper and lower surfaces of the implants and introduced into the end plates of vertebrae to secure the implants within the intradiscal space. Applicant notes that FIG. 5D is not a full implant as contended by the Examiner, but "a spacer 116 included in the cage of the implantable device" shown in FIG. 5A. (Williams, col. 7, lines 62-63). Williams does not disclose or suggest an implant having the same insertion height during insertion and maximum height when fully installed between the adjacent vertebral bodies as recited in independent claims 1, 102, and 147.

Williams teaches two distinct embodiments of the implant. A paired hemi-implant embodiment is illustrated in FIG. 2 and a single implant embodiment is illustrated in FIGS. 1 and 3A-8B. The Examiner admitted that independent claims 1, 102, and 147, as amended in the submission dated April 24, 2007, "clearly define over" the hemi-implant embodiment "shown in figure 2." (Office Action, page 2, lines 6-7). Applicant submits that neither one of the single implant embodiments of Williams meets the recitation of independent claims 1, 102, and 147 that the width of the implant is "less than approximately one-half of the maximum width of the adjacent vertebral bodies into which said implant is adapted to be inserted."

Williams does not teach that the single implants shown in FIGS. 5A-5G and 7A-7F can be deconstructed as proposed by the Examiner to form the hemi-implants of FIG. 2. Applicant maintains the position that modifying the embodiments of FIGS. 5A and 7A to be split into hemi-implants would interfere with the expansion mechanisms (e.g., 144 in FIG. 7A) for each embodiment and would render the implants unsatisfactory for the intended purpose as taught in Williams. Applicant further submits that splitting the implants of FIGS. 5A-5G into hemi-implants would destroy screw channel 109 and that reconstructing screw channel 109 on each of the resulting hemi-implants would not be obvious to one of ordinary skill in the art. Applicant submits that even if the full-size implant embodiments of FIGS. 5A-5G and 7A-7F were each improperly deconstructed into two side-by-side implants, Williams still would not disclose or suggest all of the recitations of independent claims 1, 102, and 147 for at least the reasons set forth below.

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Independent claims 1, 102, and 147 recite an interior facing side wall "extending between said opposed portions." As shown in FIGS. 5B and 7B of Williams, the interior of the implants is hollow. If these implants were each to be divided along their midlines into two implants, the interior facing sides of the resulting hemi-implants would be open. Thus, neither one of the hemi-implants would have an interior facing side wall extending between the opposed portions of the implants as recited in independent claims 1, 102, and 147. Applicant respectfully disagrees with the Examiner's assertion that "[o]ne skilled in the art in the art [sic] would find it inherent or at least obvious would [sic] dividing the various embodiments of the present invention into halves to form an interior side wall." (Office Action, page 6, lines 19-21). Applicant submits that the modification proposed by the Examiner is based not on knowledge available to one skilled in the art, but on knowledge gleaned only from Applicant's disclosure, thus amounting to impermissible hindsight. (See MPEP § 2143.01 (X) (A)).

Applicant respectfully disagrees with the Examiner's assertion that "if the species of figures 5A and 7 were made into the hemi-device, the anterior end of the device could be inserted posteriorly making the anterior end the leading end." (Office Action, page 2, lines 20-22). Applicant submits that cutting the implant of figures 5 and 7 into hemi-devices and inserting the resulting hemi-implants from the posterior direction would render the implants unsatisfactory for their intended purpose. (See MPEP § 2143.01(V): "[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Clr. 1984)").

The trailing end of the implant shown in FIG. 5A of Williams has a channel 109 "configured to receive a screw therethrough for causing the anchoring elements 108 to be pushed into the end plates of adjacent vertebrae." (Williams, col. 7, lines 43-46). The trailing end of the implant shown in FIG. 7A of Williams has a "channel formed by holes 145 and 147," through which "a fixation screw 146 can be used to drive the wedge 144 which pushes the anchor plates 132 and 134 toward end plates of adjacent vertebrae . . . and securing the device 130 intradiscally." (Williams, col. 8, lines 32-37). The leading ends of the implants of FIGS. 5A and 7A do not have such channels for receiving fixation

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screws. If the implants of FIGS. 5A and 7A were to be improperly cut in half to form hemi-implants and inserted posteriorly with the trailing ends going in first, the channels (109, 145, 147) would not be accessible to the surgeon during the surgery to permit insertion of fixation screws therethrough, making the invention unworkable.

In order for the hemi-implants formed from the full-sized implants of FIGS. 5 and 7 to be inserted posteriorly as proposed by the Examiner, the interior structure of the hemi-implants would have to be reconstructed to reverse the orientation of the internal channels such that the channels would be accessible to the surgeon during insertion. Applicant submits that the Examiner's proposed deconstruction of a full-sized implant intended for anterior insertion into two hemi-implants, reconstruction of the interior structures of the hemi-implants and insertion of resulting the hemi-implants posteriorly amount to an improper change in the principle of operation of the invention of Williams. (See MPEP § 2143.01(VI): "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)").

Applicant submits that the rejections under 35 U.S.C. §§ 102 and 103(a) in view of Williams have been overcome.

The Examiner rejected claims 1, 2, 4-8, 11-34, 36-38, 40-42, 101-130, 132-135, and 137-174 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,609,635 to Michelson ("Michelson '635") in view of U.S. Patent No. 5,192,327 to Brantigan ("Brantigan"); and rejected claims 1, 2, 4-8, 11-34, 36-38, 40-42, 101-130, 132-135, and 137-174 under 35 U.S.C. 103(a) as being unpatentable over Michelson '635 in view of Williams.

Independent claims 1, 102, and 147 recite an interior facing side wall "extending between said opposed portions." Michelson '635, alone, or when properly combined with Brantigan or Williams, does not teach or suggest such structure. Michelson '635 teaches that the interior of the full-size embodiment of the implant is hollow. (See Michelson '635, col. 6, line 55; FIG. 1). Applicant submits that even if the implant of FIG. 1 of Michelson '635 were divided along its midline to form two implants in view of the Examiner's asserted teachings of Brantigan or Williams, the interior facing sides of the resulting hemi-implants

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would be open. Thus, neither one of the resulting hemi-implants would have an interior facing side wall extending between the opposed portions of the implants as recited in independent claims 1, 102, and 147.

Applicant respectfully disagrees with the Examiner that "it would have been obvious to one having ordinary skill in the art that in some embodiments, interior walls would be formed for structural integrity." (Office Action, page 8). The Examiner has not pointed out why the structural integrity of hemi-implants resulting from cutting the full-sized implant of Michelson '635 would be compromised without an interior facing side wall. Applicant submits that the modification proposed by the Examiner is based not on knowledge available to one skilled in the art but on knowledge gleaned only from Applicant's disclosure, thus amounting to impermissible hindsight. (See MPEP § 2143.01 (X) (A)).

Applicant respectfully maintains the position with respect to the Examiner's asserted motivation to combine Michelson '635 with Brantigan for reasons set forth on page 22 of Applicant's Amendment dated January 19, 2007, incorporated by reference herein. Applicant submits that Michelson '635 already teaches a full-sized implant (FIGS. 1-17) for insertion from anterior direction and an implant (FIGS. 18-23) having a width less than one-half the maximum width of the adjacent vertebrae for insertion from posterior direction. Accordingly, one of ordinary skill in the art would not look to Brantigan or to Williams for a teaching on forming implants having a width less than one-half the maximum width of the adjacent vertebrae for insertion from posterior direction as contended by the Examiner, when such a teaching is already present in Michelson '635.

Applicant submits that the Examiner's rejections of claims under 35 U.S.C. § 103(a) over Michelson '635 in view of Brantigan and over Michelson '635 in view of Williams have been overcome.

Applicant submits that independent claims 1, 102, and 147 are patentable and that dependent claims 2, 4-8, 11-34, 36-38, 40-42, 101, and 103-130, 132-135, and 137-174, dependent from one of independent claims 1, 102, and 147, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, Applicant submits that the claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against

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this application. Applicant therefore requests the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

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By: 

Amedeo F. Ferraro

Registration No. 37,129

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (310) 286-9800
Facsimile: (310) 286-2795